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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,472	09/21/2001	Fischetti Vincent	STREPSEQ-1	6764

7590 12/19/2003

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EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 12/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/960,472	VINCENT ET AL.	
	Examiner	Art Unit	
	David J Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-275 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-275 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of the Application

[1] Claims 1-275 are pending in the application.

[2] Receipt of information disclosure statements filed January 11, 2002 and June 11, 2003, is acknowledged.

[3] Receipt of a computer readable form and paper copy of the sequence listing and a statement of sameness thereof filed January 08, 2002, is acknowledged.

Oath/Declaration

[4] It is noted that the filing dates for application 09/395,636, which applicants' claim domestic priority in the declaration and the first paragraph of the specification, are inconsistent. The declaration indicates a filing date of September 14, 2000 and the first paragraph of the specification indicates a filing date of September 14, 1999. Appropriate correction is required.

[5] The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because: The application is objected to because of alterations which have not been initialed and/or dated as is required by 37 CFR 1.52(c). A properly executed oath or declaration which complies with 37 CFR 1.67(a) and identifies the application by application number and filing date is required.

Election/Restrictions

[6] Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim(s) 1-19, 54-79, 138-154, drawn to a method for the prophylactic or therapeutic treatment of *Streptococcus pneumoniae,* a method for treating illnesses or infections of *S. pneumoniae*, and a method for the treatment of a bacterial infection caused by *S. pneumoniae* classified in class 514, subclass 2.

II. Claim(s) 20-38, 155-173, drawn to a method for treating an upper respiratory tract illness or colonization caused by *S. pneumoniae,* a method for treating the carriage of *S. pneumoniae* in an upper respiratory tract illness, classified in class 514, subclass 2.

III. Claim(s) 39-50, drawn to a method for treating bacterial meningitis caused by *S. pneumoniae*, classified in class 514, subclass 2.

IV. Claim(s) 51-53, drawn to a method for treating, preventing, or ameliorating a *S. pneumoniae* infection at a mucosal surface, classified in class 514, subclass 2.

V. Claim(s) 80-96, drawn to a method of treating eyes exposed to *S. pneumoniae*, classified in class 514, subclass 2.

VI. Claim(s) 97-108, drawn to a method for treating ear infections, classified in class 514, subclass 2.

VII. Claim(s) 109-121, drawn to a method for preventing infection of contact lens solution by *S. pneumoniae*, classified in class 514, subclass 2.

VIII. Claim(s) 122-137, drawn to a method for treating endocarditis caused by *S. pneumoniae*, classified in class 514, subclass 2.

IX. Claim(s) 174-244, drawn to a composition for treating *S. pneumoniae*, a composition for treating a respiratory tract illness caused by *S. pneumoniae,* a composition for treating bacterial meningitis caused by *S. pneumoniae,* a composition for treating eyes exposed to *S. pneumoniae,* a composition for treating ear infections, classified in class 514, subclass 2.

X. Claim(s) 245-256, drawn to a contact lens solution by *S. pneumoniae*, classified in class 514, subclass 2.

XI. Claim(s) 257-275, drawn to a method for treating a lower respiratory tract illness caused by *S. pneumoniae*, classified in class 514, subclass 2.

[7] The inventions are distinct, each from the other because:

[8] The methods of Groups I-VIII and XI are independent as they comprise different steps, utilize different products and yield different results.

[9] The composition of Group IX and the methods of Groups I-VI, VIII, and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the composition of Group IX can be used as an antigen for the production of antibodies.

[10] The contact lens solution of Group X is unrelated to the method(s) of Groups I-VI, VIII, and XI as it is neither used nor made by the method(s) of Groups I-VI, VIII, and XI.

[11] The contact lens solution of Group X and the method of Group VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, infection of contact lens solution can be prevented by sterilizing the contact lens solution with heat.

[12] The composition of Group IX is unrelated to the method(s) of Group VII as it is neither used nor made by the method(s) of Group VII.

[13] The composition of Group IX and the contact lens solution of Group X each comprises a chemically unrelated structure capable of separate manufacture, use and effect.

[14] MPEP § 803 sets forth two criteria for a proper restriction between patentably distinct inventions: (A) The inventions must be independent or distinct as claimed and (B) There must be a serious burden on the examiner. As shown above, each of the inventions of Groups I-XI are independent or distinct, thus satisfying the first criterion for a proper restriction. MPEP § 803 additionally states that a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search. Although each of inventions I-XI has the same classification, each of the inventions

recites unique limitations requiring a separate patent and non-patent literature search and/or sequence search for each Group and thus, co-examination of the inventions of Groups I-XI would place a serious burden on the examiner.

Rejoinder

[15] The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See

"Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

[16] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[17] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:00 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for submission of official papers to Group 1600 is (703) 308-4242. Draft or

informal FAX communications should be directed to (703) 746-5078. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman
Patent Examiner
Art Unit 1652

12-12-03

DAVID STEADMAN
PATENT EXAMINER